

**REMARKS/ARGUMENTS**

Claims 1-22 are pending. Claims 1-7, 10-14 and 20-22 are withdrawn from consideration. Claims 8, 9, 15-17 and 19 are rejected. Claims 9 and 18 are objected to.

Claims 1-7 have been canceled. Claim 8 has been amended changing  $Y_2$  on the left side of formula 4 to  $Y_1$ . The specification has also been amended to correct typographical errors in the text and in the formulas, specifically changing  $Y_2$  on the left side of the formulas to  $Y_1$ . Applicants respectfully assert that no new matter has been added.

In response to Examiner's request for serial numbers of co-pending applications, applicants believe the following applications comply with the Examiner's request: U.S. Serial No. 09/864,011, filed May 23, 2001; U.S. Serial No. 09/863,971, filed May 23, 2001; U.S. Serial No. 09/757,332, filed January 9, 2001; U.S. Serial No. 09/757,333, filed January 9, 2001; U.S. Serial No. 09/978,725, filed October 17, 2001; U.S. Serial No. 09/981,206, filed October 17, 2001; U.S. Serial No. 09/981,271, filed October 17, 2002; U.S. Serial No. 09/688,949, filed October 16, 2000; U.S. Serial No. 09/688,943, filed October 16, 2000; U.S. Serial No. 10/436,759, filed May 13, 2003; U.S. Serial No. 09/688,942, filed October 16, 2000; U.S. Serial No. 09/688,946, filed October 16, 2000; U.S. Serial No. 09/687,428, filed October 13, 2000; U.S. Serial No. 10/653,728, filed September 2, 2003; U.S. Serial No. 10/654,033, filed September 3, 2003; and U.S. Serial No. 09/688,947, filed October 16, 2000.

**ELECTION OF SPECIES**

Applicants affirm the elected species made during the Examiner's July 8, 2003 telephone call. In an effort to advance prosecution, applicants cancel composition claims 1-7 without prejudice, but respectfully request that the Examiner reconsider the restriction between the methods of diagnosis and therapy for the following reasons.

All the method claims are directed to the use of formula 4 in simultaneous diagnosis and therapy, as reflected in the application's title: Dye-bioconjugates for Simultaneous Optical Diagnosis and Therapeutic Applications.

The Examiner's restriction forces applicants to fragment the invention they claimed within a single claim. Under *In re Weber, Soder, & Boksay*, 198 USPQ 328, 331-32 (CCPA 1978) (copy attached) this is not permitted, because the court viewed the Examiner's restriction as tantamount to a refusal to examine. It held that the United States Patent and Trademark Office authority to restrict between claims of an application reciting one or more independent and distinct inventions, but does not have the authority to require an applicant to divide up a single claim and present it in different applications; this would allow an Examiner, rather than an applicant, to define an invention in violation of 35 U.S.C. §121, ¶2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention", emphasis added). Weber at 332. While recognizing the need for efficiency in limiting each application to one invention, the court stated that

...in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights [of the applicant] are paramount.

Section 803.02 of the MPEP states that if the claims have unity of invention, it is improper to refuse to examine "that which applicants regard as their invention". Unity of invention exists where compounds included within a Markush group share a common utility and share a substantial structural feature as being essential to that utility.

For the reasons discussed, applicants respectfully request that the Examiner reconsider the restriction requirement with respect to the method claims.

#### CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 8, 15-17 and 19 are rejected under 35 U.S.C. § 112, second paragraph because the Examiner states that when  $X_1$  and  $X_2$  are single bonds there are more than four bonds attached to the carbon atom.

Applicants believe that when  $X_1$  and  $X_2$  are single bonds,  $Y_1$  and  $Z_1$ , and  $Y_2$  and  $Z_2$  are directly attached to the carbon when  $K_1$  and  $K_2$  are CH. This results in only four bonds attached to the carbon atom. However, if applicants have misunderstood, the Examiner is invited to contact applicants' undersigned representative.

**CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

Claims 8, 15-17, and 19 are rejected under 35 U.S.C. § 103(a) as obvious over Turner, finding that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Turner and generate a species encompassed by formula 4 used in a diagnosis method because Turner discloses a diagnostic method where a composition encompassed by formula 4 is administered to a subject to diagnose neurodegenerative diseases such as Alzheimer's disease.

Applicants respectfully disagree. The claimed method of diagnosis administers the compound of formula 4 which has three components: (1) a targeting component, (2) a phototherapy component, and (3) a photodiagnostic component (page 4, line 21 to page 5, line 1; page 11, lines 1-5). The Examiner's restriction artificially separated applicants' invention of performing a tandem diagnostic and therapeutic procedure by administering formula 4.

While applicants do not change their basic invention, the Election requires choosing between phototherapy by administering formula 4 and photodiagnosis by administering formula 4, when the invention is for combined phototherapy and photodiagnosis.

Applicants respectfully assert that the Examiner cannot now use the restriction to further determine that substituent groups of formula 4 are only obvious variations. In administering the compound of formula 4 for a method of diagnosis (the claims elected responsive to the Examiner's new restriction), the

entire compound of formula 4 is administered. Formula 4 is not rendered obvious over Turner for at least the following reason.

Turner discloses compounds for *in vivo* and *in vitro* diagnosis of neurodegenerative diseases; with Turner's components A and B limited to beta-amyloid plaque binders. The Examiner has not established a *prima facie* case of obviousness by showing where Turner teaches, suggests, or motivates including components such that the compound administered for a diagnostic procedure contains applicants' formula 4 components for targeting and tandem phototherapy and photodiagnosis.

In addition, the compound of Turner has a maximum of two biomolecules and there is no teaching or suggestion as to where on the dye molecule these are attached. In contrast, applicants' formula 4 has four biomolecules attached to the nitrogen in the five-membered rings of the dye molecule. Thus, applicants respectfully request that the rejection be withdrawn.

#### **CLAIM OBJECTIONS**

Claims 9 and 18 are objected to as being dependent upon a rejected base claim. For the reasons stated above, applicants believe that these claims and the remaining method claims are allowable and respectfully request that the objection be withdrawn.

**CONCLUSION**

For the foregoing reasons, applicants submit that the claims are patentable, and an early Notice of Allowance is respectfully requested.

Applicants know of no fee due with this submission. However, if any fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account No. 23-3000.

The Examiner is invited to contact applicants' undersigned representative with any questions.

Respectfully submitted,

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